Reviewer's report

Title: An effective multisource informed consent procedure for research and clinical practice: an observational study on patient understanding and awareness as a research stakeholder in a cancer biobank

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Reviewer: Julien Mancini

Reviewer's report:

The authors had surveyed 430 patients from a single institution using a self-administered questionnaire. The main purpose of the study was to evaluate the efficiency of a multisource informed consent procedure for enrolment in a cancer biobank.

The patients' surveys on this topic remain scarce and the approach may be of interest, however some issues should be carefully addressed. Although it is of transient importance because of the high level of resource needed for such a multisource approach, the authors did not really studied the efficiency of their approach but only the understanding and awareness of patients exposed to the consent procedure. The other main limitations of this survey are the use of a homemade questionnaire with an unclear timing and the lack of comparison with the previous surveys among cancer patients.

- Major Compulsory Revisions:

1. The term "efficiency" used in the abstract and in the end of the introduction should be replaced by "effectiveness". Moreover the financial consequences of proposing a multisource approach should be more clearly discussed. The multisource approach is probably effective as shown by the authors. However there is still a debate on the need of collecting informed consent for biobanking, and some authors propose an ‘opt-out’ or ‘opt-out+’ procedure (Vermeulen et al. Br J Cancer 2009; Riegman and van Veen Human Genetics 2011). A multisource approach requires a lot of resources particularly if the biological samples are not used at the end. Therefore, the cost-effectiveness or efficiency of such a multisource approach might be a more interesting area of research.

2. The review of the literature is clearly insufficient and not updated. In the discussion section a review published in 2004 was considered recent. Moreover, most of the articles in the reference list do not concern cancer patients or the specific context or biobanking residual tissues (Riegman and van Veen Human Genetics 2011). Nevertheless, cancer patients might have a different view on biobanking compared to general population. Understanding and awareness might also be altered when cancer patients are asked for consent, particularly when the consent is asked at the time of their cancer diagnosis. The surveys among cancer patients remain scarce but several articles have been published

3. A comparison between the 430 respondents and the 120 non respondents should be provided.

4. Authors should explain how their homemade questionnaire was validated (cf. Methods section). The following sentence from the discussion is also disputable: “There is no proper standard methodology for the evaluation of the informed consent process.” An adaptation of the “quality of informed consent measure” (QuIC; Ormond et al. Am J Med Genet 2008) might have been used, after tailoring to the specific context of cancer biobanking. At the end, the homemade questionnaire is quite limited and I’m unsure about the adequacy of the framing of the questions and responses. For example, the framing of the question about awareness (“Are you aware that…”) might be spontaneously associated with high level of awareness. In the same way caution should be added to the following sentence of the discussion (“A survey among participants in another biobank, for example, showed that only 33.3% of them gave correct answers as to the aim of the study [2].”) as the questions about the aims were much more complicated in the Toccaleli et al. survey.

5. The results are difficult to discuss because the time elapsed between consent and the response to the questionnaire is not provided. It is mandatory for studying awareness of consent. The recall of the signature is probably higher when using a multisource approach rather than an uncontrolled dissemination of a consent form (Mancini et al. J Natl Cancer Inst 2011). But awareness should not be studied to close from the procedure to have an interest.

6. The first two sentences of the discussion section (“As per laws...”) should also be discussed. The laws are different across the countries and the ‘opt-in’ procedure is still debated (Giesbertz et al. PLoS Biol 2012).

- Minor Essential Revisions:

7. Table 4, first comparison (awareness): A trend test might be significant here.

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Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests:

I declare that I have no competing interests.